

## Step Therapy Edit Criteria Proposal

Drug/Drug Class: **Proton Pump Inhibitor Step Therapy Edit**

Prepared for:  
Prepared by: **Missouri Medicaid**

☐ **New Criteria**

☒ **Revision of Existing Criteria**

### Executive Summary

**Purpose:** Reduce the average cost per prescription claim for Proton Pump Inhibitors by implementing a preferred drug product, Over-the-Counter (OTC) Prilosec®.

**Why was this Issue Selected:** During the twelve-month calendar period of June 2002 to May 2003, 182,659 claims were paid for PPI therapy at a cost of \$20,914,521. This dollar amount represents approximately 2.3% of the total prescription drug benefit spend over that same calendar period. Potential cost savings using OTC Prilosec® as the reference product is \$8.4 million per year.

	<b>Drug</b>	<b>Claims</b>	<b>AWP</b>
<b>Program-specific information:</b>	• OTC Prilosec®	--	<b>\$0.77</b>
	• Omeprazole (PRILOSEC®)	34,546	\$4.13
	• Esomeprazole (NEXIUM®)	35,988	\$4.57
	• Pantoprazole (PROTONIX®)	32,521	\$3.83
	• Rabeprazole (ACIPHEX®)	9,993	\$4.46
	• Lansoprazole (PREVACID®)	69,611	\$4.77

**Setting & Population:** All patients prescribed Proton Pump Inhibitors other than the reference drug(s).

**Type of Criteria:**

<input type="checkbox"/> <b>Increased risk of ADE</b>	<input checked="" type="checkbox"/> <b>Non-Preferred Agent</b>
<input checked="" type="checkbox"/> <b>Appropriate Indications</b>	<input type="checkbox"/>

**Data Sources:**

<input type="checkbox"/> <b>Only administrative databases</b>	<input checked="" type="checkbox"/> <b>Databases + Prescriber-supplied</b>
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## Approval Criteria

### Reference Drug Product: OTC Prilosec® (Omeprazole)

- Patient currently approved for a non-reference PPI product that demonstrates therapy compliance,
- Trial and failure on Ranitidine Tablets (or approved H2 antagonist),
- Patient has documented adverse drug event to the reference PPI product,
- Patient has documented therapeutic failure to the reference PPI product,
- Patient currently prescribed a non-reference PPI product with history of an adequate trial period with reference PPI product

Approval Diagnoses				
Condition	Submitted ICD-9 Diagnoses	Inferred Drugs	Date Range	Client Approval (Initials)
Barrett's Esophagus	530.2	--	720 days	
Drug-Induced Ulcer	531.40	--	720 days	
Zollinger Ellison Syndrome	251.5	--	720 days	
Mastocytosis	202.6 – 202.68	--	720 days	
Erosive Esophagus	530.1 – 531.10	--	720 days	
Endocrine Neoplasm	227 237	--	720 days	
Peptic Ulcer Disease	533.0 - 533.9	--	720 days	
GERD	530.81 530.10 – 530.19	--	720 days	
Hiatal Hernia	551.3 552.3 – 553.3	--	720 days	
Upper GI Bleed	578.0 – 578.9	--	720 days	
Pancreatic Insufficiency	579.4	Pancreatic Enzymes	720 days	
Cystic Fibrosis/Pancreatic Insufficiency w/ Steatorrhea	277.00 - 277.03 577.8 579.4	--	720 days	

### Additional Approval Criteria information:

- Positive H-Pylori –
  - Requires concurrent PUD diagnosis
  - No required H2 antagonist or reference PPI trial (entire class available or Prevpac)

- GERD – Nursing home patients are approved for reference PPI without mandatory trial/failure on H2 antagonist.
- Hiatal Hernia – requires concurrent GERD diagnosis
- Pancreatic Insufficiency – requires pancreatic enzyme therapy within the last 45 days
- Cystic Fibrosis – DX = pancreatic insufficiency with or without steatorrhea
  - Pancreatic enzyme therapy within the last 45 days
- Chemotherapy Induced Gastropathy – DX = CA (or inferred CA) with gastritis (gastropathy)
- Pregnancy – Reference PPI trial not mandatory (entire PPI class available)

## Denial Criteria

- Lack of evidence of therapeutic trial or failure period on Ranitidine Tablets (or approved H2 antagonist),
- Lack of evidence of therapeutic trial or failure period of reference PPI product,
- Lack of compliance to non-reference PPI therapy,
- Documented ADE to reference PPI product.

## Required Documentation

Appropriate Diagnosis  
MedWatch form:

X

Progress notes:


## Disposition of Edit

- **Denial:** Exception 681 “Step Therapy”

## References

1. Facts and Comparisons, p.1135-38C. 2003.
2. USPDI, Micromedex, 2003.
3. “Evidenced Based Medicine Analysis: Proton Pump Inhibitors”, UMKC-DIC, May 2003.
4. “Over-The-Counter Omeprazole (Prilosec OTC)”, The Medical Letter, Vol. 45 (Issue 1162), August 4, 2003.